

Complete Summary

GUIDELINE TITLE

Prevention of Rh D alloimmunization.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Prevention of Rh D alloimmunization. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1999 May. 8 p. (ACOG practice bulletin; no. 4). [58 references]

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of December 2004, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Rh D alloimmunization

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To provide direction for the appropriate and efficient management of patients at risk in order to further decrease the frequency of Rh D alloimmunization

TARGET POPULATION

Pregnant Rh D-negative women

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention

1. Repeat antibody screening at 28 weeks of gestation
2. Antenatal anti-D immune globulin administration
3. Screening Rh D-negative women who deliver Rh D-positive infants for excessive fetomaternal hemorrhage
4. Postpartum anti-D immune globulin administration

MAJOR OUTCOMES CONSIDERED

- Reasons for failure to prevent Rh D alloimmunization
- Potential shortage of anti-D immune globulin
- Cost-effectiveness of Rh D prophylaxis programs

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1980 and December 1998. The search was restricted to articles published in the English language. Priority was given to the articles reporting results of original research although review articles and commentaries also were

consulted. Abstracts of research presented at symposiums and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and ACOG were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II -1 Evidence obtained from well-designed controlled trials without randomization

II -2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II -3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Levels of Recommendations

- A. The recommendation is based on good and consistent scientific evidence.
- B. The recommendation is based on limited or inconsistent scientific evidence.
- C. The recommendation is based primarily on consensus and expert opinion.

COST ANALYSIS

The cost-effectiveness of preventing perinatal mortality and morbidity secondary to Rh D hemolytic disease of the newborn is an important consideration. Economic analysis of anti-D immune globulin prophylaxis is based on the cost of anti-D immune globulin and the number of alloimmunizations that would be prevented. In 1977, the McMaster Conference concluded that routine postnatal prophylaxis was cost-effective but that routine antenatal treatment should be undertaken only if supplies of anti-D immune globulin were adequate and if cases of hemolytic disease of the newborns occurred that might have been prevented by antenatal treatment. Some experts concluded that antenatal prophylaxis is effective only in primigravidas, and the debate regarding the cost-effectiveness of antenatal prophylaxis of all pregnant women remains unsettled. The Scottish National Blood Transfusion Service has concluded that the administration of 100 micrograms of anti-D immune globulin at 28 weeks and 34 weeks of gestation is cost-effective only in primigravidas. Others estimate that the most cost-effective antenatal regimen is a single dose of 250 micrograms of anti-D immune globulin at 28 weeks of gestation.

The use of anti-D prophylaxis in the case of certain clinical events is even more controversial. For example, the risk of Rh D alloimmunization from threatened abortion in the first trimester is uncertain, though probably very small. The cost-effectiveness of anti-D immune globulin for threatened abortion, which has never been studied, is questionable.

In summary, the cost-effectiveness of antenatal Rh D immune globulin to all Rh D-negative pregnant women and in all circumstances wherein fetomaternal hemorrhage might occur has not been proved. Available data support that third-trimester antenatal prophylaxis is cost-effective in primigravidas. As long as the supply of anti-D immune globulin is adequate and data do not exist to support other recommendations, most experts believe that it is unethical to withhold anti-D immune globulin from any patient at risk of Rh D alloimmunization. Recommendations for the use of anti-D immune globulin in this guideline will be made accordingly.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

The Rh D-negative woman who is not Rh D-alloimmunized should receive anti-D immune globulin:

- At approximately 28 weeks of gestation, unless the father of the baby is also known to be Rh D negative
- Within 72 hours after the delivery of an Rh D-positive infant
- After a first-trimester pregnancy loss
- After invasive procedures, such as chronic villus sampling, amniocentesis, or fetal blood sampling

The following recommendations are based primarily on consensus and expert opinion (Level C):

Anti-D immune globulin prophylaxis should be considered if the patient has experienced:

- Threatened abortion
- Second- or third-trimester antenatal bleeding
- External cephalic version
- Abdominal trauma

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II - 1 Evidence obtained from well-designed controlled trials without randomization

II -2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II -3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

- A. The recommendation is based on good and consistent scientific evidence.
- B. The recommendation is based on limited or inconsistent scientific evidence.
- C. The recommendation is based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Antenatal and postpartum administration of anti-D immune globulin is associated with dramatic decrease in alloimmunization and subsequent hemolytic disease.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 May (reviewed 2004)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the [ACOG Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 14, 2005.

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